

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency

Office of Pesticide Programs

**MEMORANDUM**

3/3/2020

**SUBJECT:** Product Chemistry Review for **Synergex** EPA Reg. No.: **1677-250**

**FROM:** Lynette T. Umez-Eronini  
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**THRU:** Karen P. Hicks, Team Leader  
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Antimicrobials Division (7510P)

03/03/2020

**TO:** Zeno Bain, PM Team 33 / Aline Heffernan  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Registrant: Ecolab Inc.  
Action code: A570  
Agency Due Date:  
3/6/2020  
DP No.: 455044  
Submission No.: 1042052  
E-Sub No.: 43657  
Classification: EP  
Process: Nonintegrated  
system  
Pesticide type:  
Disinfectant

MRID(s):50968200, 50968204

| Formulation from label |            |                      |          |
|------------------------|------------|----------------------|----------|
| PC code(s)             | CAS #(s)   | Active Ingredient(s) | % weight |
| 000595                 | 7722-84-1  | Hydrogen peroxide    | 10.70    |
| 063209                 | 33734-57-5 | Peroxyoctanoic acid  | 0.63     |
| 063201                 | 79-21-0    | Peroxyacetic acid    | 2.38     |
|                        |            | Other Ingredients    | 86.29    |
|                        |            | Total                | 100.00   |

1677-250\_D455044\_Synergex

## I. BACKGROUND

The Registrant, Ecolab Inc., has submitted an minor formulation amendment for their product: Synergex EPA Reg. No. 1677-250. The amendment is to review the 830.6317 Storage Stability and 830.6320 Corrosion Characteristics studies.

## II. RELEVANT DOCUMENTS

|   | RECEIVED                            | N/A                                 |
|---|-------------------------------------|-------------------------------------|
| EPA FORM 8570-1– Application for Pesticide – Amendment (10/16/2019) | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| Cover letter (10/16/2019)   | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| EPA FORM 8570-35 – Data Matrix (10/16/2019)                         | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| Transmittal document (10/16/2019)                                   | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| Proposed CSF  | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
| Proposed label, (10/16/2019)  | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| Certification for Pilot Fragrance Notification Program              | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
|   | <input type="checkbox"/>            | <input type="checkbox"/>            |
| REFERENCED: CSF BASIC , (10/20/2014)                                | --                                  |                                     |
| REFERENCED: LABLE, (8/22/2017)                                      | --                                  |                                     |
| Comments:   |                                     |                                     |

## III. FINDINGS

### a. Product Formulation:

|                       | TGAI                     | MUP                      | EUP                                 | Food use                            | Non-food use             |
|-----------------------|--------------------------|--------------------------|-------------------------------------|-------------------------------------|--------------------------|
| Non-integrated        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            | <input type="checkbox"/> |
| Integrated            | <input type="checkbox"/> | <input type="checkbox"/> | <input checked="" type="checkbox"/> | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
|                       |                          |                          |                                     |                                     |                          |
| Active Ingredients(s) |                          |                          | Nominal                             | Upper limit                         | Lower limit              |
| Hydrogen peroxide     |                          |                          | 10.70                               | 11.55                               | 9.75                     |
| Peroxyoctanoic acid   |                          |                          | 0.63                                | 0.78                                | 0.49                     |
| Peroxyacetic acid     |                          |                          | 2.38                                | 2.72                                | 2.04                     |

|   | YES                                 | NO                                  | N/A                                 |
|---|-------------------------------------|-------------------------------------|-------------------------------------|
| 1. The certified limits of all ingredients are within 40 CFR standard certified limits.                                       | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |                                     |
| 2. Wider certified limits were previously requested and rationale was accepted.   | <input type="checkbox"/>            | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
| 3. The nominal concentration(s) of the active ingredient is in agreement with the label.                                      | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |                                     |
| 4. The chemical IDs and analytical information for density, pH, and flammability are consistent with Series 830 Group B data. | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |                                     |
| 5. All inert ingredients are approved for food use pesticide formulations.  | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            |
| 6. The impurities present >0.1% are identified.   | <input type="checkbox"/>            | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
| 7. Impurities of toxicological significance have an upper certified limit.  | <input type="checkbox"/>            | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |

b. Product Label:

|   | Yes                                 | NO                                  | N/A                                 |
|---|-------------------------------------|-------------------------------------|-------------------------------------|
| <i>The formula contains one of the following:</i>   |                                     |                                     |                                     |
| 1. 10% or more of petroleum distillate  | <input type="checkbox"/>            | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| 2. 1.0% or more of methyl alcohol   | <input type="checkbox"/>            | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| 3. Sodium nitrite at any level  | <input type="checkbox"/>            | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| 4. A toxic list 1 inert at any level  | <input type="checkbox"/>            | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| 5. Arsenic in any form  | <input type="checkbox"/>            | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| 6. If yes to 1-5, then the inert ingredient list contains a relevant footnote   | <input type="checkbox"/>            | <input checked="" type="checkbox"/> | <input type="checkbox"/>            |
| 7. Appropriate warning statements regarding flammability or explosive characteristics of the product are included on the label  | <input type="checkbox"/>            | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |
| 8. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses. | <input checked="" type="checkbox"/> | <input type="checkbox"/>            | <input type="checkbox"/>            |
| 9. The product requires an expiration date at which time the nominal concentration falls below the lower certified limit.   | <input type="checkbox"/>            | <input type="checkbox"/>            | <input checked="" type="checkbox"/> |

**IV. Additional Findings**

1. Basic CSF, dated 10/20/2014 and label, dated 8/22/2017 are used as references.
2. Support for wider certified limits for the active ingredients and some of the inert ingredients

1677-250\_D455044\_Synergex

was previously provided and found acceptable (see Chemistry Review for 1677-ELN\_D424059\_Synergex, dated April 10, 2015).

3. A statement of Good Laboratory Practice Standards outlined in 40 CFR Part 160 is provided (See MRID 50968204).
4. The 830.6317 Storage Stability and 830.6320 Corrosion Characteristics studies were conducted in High Density Polyethylene (HDPE) bulk containers at a temperature range from 20.6°C – 28.2°C at 0, 1, 2, 3, 4, 5, 6, 8, 10, 12, 14, 16, 18, and 20 months.
5. Color and physical state of the test substance and container that contained the test substance were tested visually.
6. No crazing nor cracking of the high density polyethylene container and closure were observed and the test substance was clear to light yellow throughout the 20 months study.
6. Chemical analysis of the active ingredients was done by titration. Analysis was made on one sample that was taken from the bulk container, except in one case. An average of 3 measurements were taken and reported for hydrogen peroxide at 14 months. Titration results are shown in the table below.

Table: Titration Analysis of Hydrogen Peroxide, Peroxyacetic Acid, and Peroxyoctanoic Acid

| Time, month | Hydrogen Peroxide (H <sub>2</sub> O <sub>2</sub> ), % by wt |        | Peroxyacetic Acid (POAA), % by wt |      | Peroxyoctanoic Acid (POOA), % by wt |      |
|-------------|---|--------|-----------------------------------|------|-------------------------------------|------|
| 0           | 11.01   | 11.00  | 2.54                              | 2.49 | 0.61                                | 0.60 |
| 1           | 11.07   | 10.98  | 2.5                               | 2.5  | 0.59                                | 0.58 |
| 2           | 10.90   | 10.92  | 2.4                               | 2.4  | 0.62                                | 0.59 |
| 3           | 10.87   | 10.88  | 2.4                               | 2.4  | 0.57                                | 0.58 |
| 4           | 10.79   | 10.79  | 2.5                               | 2.5  | 0.57                                | 0.57 |
| 5           | 10.76   | 10.72  | 2.5                               | 2.4  | 0.59                                | 0.59 |
| 6           | 10.62   | 10.63  | 2.5                               | 2.5  | 0.57                                | 0.58 |
| 8           | 10.51   | 10.51  | 2.33                              | 2.38 | 0.56                                | 0.55 |
| 10          | 10.36   | 10.41  | 2.30                              | 2.31 | 0.54                                | 0.55 |
| 12          | 10.30   | 10.31  | 2.29                              | 2.33 | 0.55                                | 0.58 |
| 14          | 10.12*  | 10.11* | 2.29                              | 2.29 | 0.56                                | 0.56 |
| 16          | 10.03   | 10.06  | 2.31                              | 2.31 | 0.54                                | 0.52 |
| 18          | 9.90  | 9.84   | 2.24                              | 2.21 | 0.53                                | 0.53 |
| 20          | 9.71  | 9.67   | 2.27                              | 2.24 | 0.51                                | 0.50 |

\*Indicate the average of 3 measurements

| <u>Active</u>       | <u>Nominal</u> | <u>Certified Limit</u> |
|---------------------|----------------|------------------------|
| Hydrogen peroxide   | 10.70%         | 11.55% - 9.75%         |
| Peracetic acid      | 2.38%          | 2.72% - 2.04%          |
| Peroxyoctanoic Acid | 0.63%          | 0.78% - 0.49%          |

1677-250\_D455044\_Synergex

7. Note: The results of the long-term 20 months storage stability and corrosion studies herein show the concentration of all active ingredients lie within the Certified Limits over the 20 months testing period, except hydrogen peroxide at 20 months. Since the 830.6317 and Storage Stability and 830.6320 Corrosion Characteristics guidelines recommend testing for a period of every 3 months up to a year and if continued beyond 1 year, then every 6 months thereafter, then the 830.6317 and Storage Stability and 830.6320 Corrosion Characteristics guidelines for the current product have been met.

## **V. Conclusion**

The Product Science Branch of Antimicrobials Division finds the 830.6317 Storage Stability and 830.6320 Corrosion Characteristics guidelines to be acceptable.